



# Ethical Considerations in Research Involving Children

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# What's at stake

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- Human research involves *using* human subjects.
- Often *imposes risks* on subjects.
- Much of the justification: PROSPECT FOR SIGNIFICANT BENEFIT TO SOCIETY
- Paramount *subject-centered* values:
  - SELF-DETERMINATION
  - WELL-BEING



# Goals, rights, and protection from harm

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- May understand these values in terms of goals, rights & protection from harm.
- *Goal* of societal benefit is undeniably valuable.
- But what means to this end are ethically permissible?
- Crucial factor in setting limits: *rights* of (prospective) subjects.



# The rights of human subjects

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- A RIGHT TO ADEQUATE PROTECTION FROM HARM
- Competent adults also have A RIGHT TO SELF-DETERMINATION.
- So, in a way, do children & adults w/compromised decision-making capacity.
- Rights as *side-constraints* or *trumps*.
- Rights are NOT to be balanced against goals of research.



# Specifying the rights of minor subjects

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- How should we think about the rights of children in research?
- First, bear in mind:
  - Their vulnerability to domination & exploitation by adults: parents, guardians, authority figures including researchers
  - Their limited decision-making capacity.



# Relevant decision-making standards

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- Lexically ordered decision-making standards :
  - INFORMED CONSENT for competent adults or subjects determined to have (sufficient) decision-making capacity
  - BEST INTERESTS for children or adults who lack (sufficient) decision-making capacity.
  
- Factors complicating interpretation:
  - Children's partial decision-making capacity
  - Ambiguity of "best interests"



# Capacity & autonomy

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- Informed-consent standard rests on DECISION-MAKING CAPACITY.
- This = capacity to make a decision (of the relevant kind) *autonomously*.
- Theoretical controversy over what AUTONOMOUS ACTION involves



# Suggested analysis for informed consent

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- Conditions for informed consent—(sufficiently) autonomous authorization—for participating in research:

*One provides valid (voluntary, informed) consent if & only if one consents to participate in a protocol*

*(1) intentionally,*

*(2) w/sufficient understanding of the nature of the study, its risks & possible benefits, and*

*(3) sufficiently freely of (a) external constraints & (b) internal constraints.*



# The importance of children's assent

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- Some mature minors are probably capable of informed consent.
- All other minors are not. Tend to lack sufficient understanding and/or sufficient freedom from external & internal constraints.
- But autonomy & capacity come in degrees.
- So we should take a minor's wishes into account.
- Common practice of requiring minor subjects' *assent* (along w/ proxy permission) is sound. Exceptions are possible.



# Understanding best interests

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- The BI standard applies to nearly all minors.
- Generally understood to permit research on children when
  - only minimal risk,
  - “a minor increase over minimal risk” (if certain conditions are met), or
  - direct medical benefit that compensates for the risk
- Note: If we take “best interests” in literal, maximizing sense, BI standard will prohibit research on children whenever they face *any* risks not offset by prospect of benefits to them.
- Suggestion: Don’t take “best interests” so literally.



# Children's essential interest in adequate protection from harm

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- BI standard should be understood as protecting minor subjects' *essential* interests.
- Extends idea that parents owe their children protection of their essential interests—including *adequate protection from harm*.
- But what constitutes adequate protection from harm in the context of pediatric research?



# Recommended standard

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- *Children may be involved in promising research that*
  - *Offers direct medical benefit that compensates adequately for any risk; or*
  - *No direct medical benefit, but relatively minor risks compatible w/ protections responsible parents would afford their children.*
- Pediatric research outside these categories violates children's right to adequate protection from harm.